

Remarks

Claims 37-62 are pending. Claims 48-50 and 53 have been withdrawn. Claims 1-36 have been cancelled. Claim 39 has been amended. No new matter has been added.

Claim Objection

Claim 39 is objected to for being dependent on itself. Applicants have amended the claim to correct this inadvertent error.

In view of the foregoing, Applicants respectfully request withdrawal of the objection.

Rejections Under 35 U.S.C. §112

Claims 37-47, 51-52 and 54-62 are rejected under 35 U.S.C. §112, second paragraph for allegedly being indefinite. Applicants respectfully disagree.

The Examiner contends that the term “peptide load” is unclear. However, Applicants point out that the term “peptide load” is defined in the instant specification as the number of moles of peptide per mole of the carrier (see paragraph 4, lines 1-3 of the instant specification as published as US Publication 2009/0104220).

The test of definiteness is whether one skilled in the art would understand the bounds of the claim when read in light of the specification. Orthokinetic Inc. v. Safety Travel Chairs, Inc., 806 F.2d 1565, 1 U.S.P.Q.2d 1081 (C.A.F.C. 1986). Applicants believe one skilled in the art would not find the term ambiguous, particularly in light of the given definition.

Claims 37-47, 51-52 and 54-62 are rejected under 35 U.S.C. §112, first paragraph for allegedly failing to comply with the written description requirement. Applicants respectfully disagree.

The Examiner contends that the specification provides written description for only for the 5 modified HA peptides conjugated to OMPC that are shown in the Examples of the specification. Applicants point out that under the applicable case law, it is improper to limit Applicants to the specific example presented, notwithstanding the disclosure and enablement of a broader invention. See In re Anderson, 176 U.S.P.Q. 331, 333 (C.C.P.A. 1973); In re Kamal, 158 U.S.P.Q. 320, 323 (C.C.P.A. 1968).

Furthermore, the Examiner believes that, because the broadest claims do not specify particular peptides or particular carriers, the specification does not disclose enough species in the claimed genus. The Examiner then cites to various places in the specification that allegedly show that use of peptides with different characteristics may affect the outcome of the claimed methods.

Applicants believe that the specification provides adequate teaching for one skilled in the art to use the claimed methods. The claimed methods specify that peptide load and/or solubility are increased because of the peptide modification. Those modified peptides that do not meet this claim limitation are outside of the scope of the claims. One skilled in the art could determine, using routine techniques, whether or not a peptide c-conjugate pair falls within the scope of the claims or not. An invention is enabled even though the disclosure may require some routine experimentation to practice the invention. Hybritech Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 1384, 231 U.S.P.Q. 81, 94 (Fed. Cir. 1986).

According to applicable case law, an inventor is not required to disclose “a test of every species encompassed by their claims” even in an unpredictable art. In re Angstadt, 190 U.S.P.Q. 214, 218 (C.C.P.A. 1976). Applicants have provided direction to those skilled in the art on how to modify a peptide such to increase its peptide load and/or solubility. Even if some of the peptides with lowered isoelectric points did not have increased load when conjugated to some carriers, the claims are not necessarily invalid. ‘It is not a function of the claims to specifically exclude . . . possible inoperative substances . . . ‘ Atlas Power Co. v. E. I. Du Pont de Nemours & Co., 750 F.2d 1569, 224 USPQ 409 (Fed. Cir. 1984) citing In re Dinh-Nguyen, 492 F.2d 856, 858-859, 181 USPQ 46, 48 (CCPA 1974)(emphasis omitted).

Finally, the Examiner contends that the biomolecules made by the claimed methods are not adequately described because they are described only by functional characteristics and cites MPEP §2163 for the proposition that a biomolecule that is described only by a functional characteristic does not have written description (see the paragraph spanning pages 4-5 of the Office Action mailed February 25, 2010). Applicants respectfully disagree with this contention. There is a requirement that the peptides for use in conjugation have been altered by lowering their isoelectric point. This is not merely a functional description but rather an alteration with a specific outcome that can be tested by one skilled in the art using routine techniques. While Applicants have not described which particular residues of the peptides to alter or what the specific modifications should be, the teaching in the specification rises above a mere recitation of a desired outcome (*i.e.*, that the peptide load is increased). Rather, the specification specifically teaches how one skilled in the art could accomplish the desired outcome - namely by lowering the isoelectric point of the peptide. The isoelectric point of a peptide is a concept that

is well known in the art. Routine techniques can be used to alter a peptide and then quantify its isoelectric point.

Even assuming *en arguendo* that a direction to lower a peptide's isoelectric point is a functional characteristic, Applicants contend that there is a correlation between the function and structure of the biomolecule -- namely that the act of lowering the isoelectric point is what allows the peptide to be better conjugated to the carrier.

In view of the foregoing, Applicants respectfully request withdrawal of the rejections under §112.

Conclusion

It is believed that the claims now pending are in condition for allowance. Early and favorable action by the Examiner is earnestly requested.

Authorization

The Commissioner is hereby authorized to charge to deposit account 13-2755 \$130.00 to pay the fee under 37 C.F.R. §1.136(a) for an Extension of Time for one month. Additionally, the Commissioner is hereby authorized to charge any additional fees which may be required for consideration of this Amendment to deposit account 13-2755.

Respectfully submitted,

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